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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/137,059 08/20/98 JOHNSTON

B A-65200/WHD/

EXAMINER

HM12/0214

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ART UNIT

PAPER NUMBER

1635

DATE MAILED:

02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/137,059

Applicant(s)

JOHNSTON ET AL.

Examiner

Mary Schmidt

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

1. Claim 23 is pending. In view of the claim amendments in the Amendment filed 12/01/00, the following 35 U.S.C. 112 rejections are newly made:

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 23 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in view of the amendments filed 12/01/00.

Claim 23 was amended to recite "a method for detecting the presence of a target molecule in a composition suspected of containing said target molecule, said method comprising: contacting said composition with a catalytically inactive RNA molecule which binds to said target molecule, wherein binding of said catalytically inactive RNA molecule to said target molecule allows said catalytically inactive RNA molecule to become catalytically active towards a substrate other than the target molecule, wherein the action of the catalytically active RNA molecule on the substrate is indicative of the presence of said target molecule in said composition."

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The metes and bounds of the structure of the target molecule, the catalytic RNA (inactive and active states) and the substrate are not clear from the claim as written. Prior to the current amendment of the claim, it appeared from the claim and the specification as filed that the catalytic RNA acted on the target molecule as, for example, ribozymes are known to function in the art. In fact, the specification as filed refers to antisense and ribozyme constructs with which it appears that both function to bind the "target" and improve binding via a 'padlock' structure. Thus it is not clear from the specification as filed the structure of the claimed invention is such that one skilled in the art has a clear idea of the steps involved in the methods as broadly claimed.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In view of the 35 U.S.C. 112, second paragraph, rejection above, it is not clear what the metes and bounds of the structure of the claimed invention is, and thus it is not enabled for one skilled in the art to make and use the invention as claimed.

Specifically, the specification teaches some constructs by way of example, such as the Antisense-Triplex-Ribozyme, which have improved binding capacity over an Antisense-Triplex to

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the same "target". However, it is not clear how these types of constructs function to "act" on any other substrate. On page 4 of the specification, it is taught that the "sense-antisense hybridization is unstable in the absence of the clasp molecule... the ends of the padlock DNA create a binding site for c-myc." And on page 3 it is taught that "the ball represents any of various ways for the ends of this molecule to interact following hybridization with the target with creation of at least one turn of helical interwinding.... In one embodiment, the ball comprises a hairpin ribozyme moiety." In the specific case of the ATR example, it is not clear that the ATR (specifically the R, the ribozyme) acts on a substrate other than the target which the ATR complex binds. And since the claim specifies a transition from a catalytically inactive to a catalytically active RNA, it is not clear what substrate the RNA is cleaving. The example of the c-myc binding does not qualify as a transition from a catalytically inactive to active RNA.

Therefore, in view of the above reasons, one skilled in the art would necessarily practice an undue amount of experimentation to make and use the invention as broadly claimed

6. In view of the above new rejections, the 35 U.S.C. 102 rejections are withdrawn at this time.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, Katrina Turner, whose telephone number is (703) 305-3413.

M. M. Schmidt  
February 12, 2001



REMY YUCEL, PH.D  
PRIMARY EXAMINER